(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization International Bureau



(43) International Publication Date 30 January 2003 (30.01.2003)

PCT

(10) International Publication Number WO 03/007783 A2

(51) International Patent Classification7:

(21) International Application Number: PCT/US02/22005

(22) International Filing Date: 13 July 2002 (13.07.2002)

(25) Filing Language:

English

A61B

(26) Publication Language:

English

(30) Priority Data:

09/906,463

16 July 2001 (16.07.2001) US

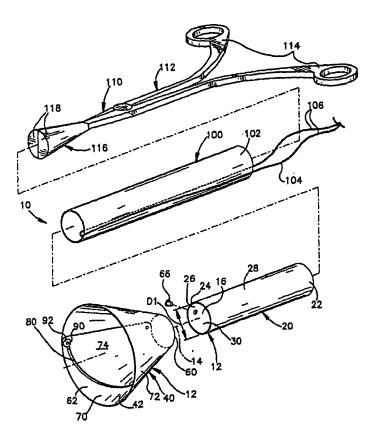
- (71) Applicant: ENDIUS INCORPORATED [US/US]; 23 West Bacon Street, Plainville, MA 02762 (US).
- (72) Inventors: DAVISON, Thomas, W.; 83 Farm Hill, North Attleboro, MA 02760 (US). SHER, Adam; 30 Juniper

Road #43, North Attleboro, MA 02760 (US). UNGER, John, D.; 20 Farm Hill Road, Wrentham, MA 02093 (US).

- (74) Agent: TAROLLI, James, L.; Tarolli, Sundheim, Covell, Tummino & Szabo L.L.P., 526 Superior Avenue, Suite 1111, Cleveland, OH 44114 (US).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),

[Continued on next page]

(54) Title: SURGICAL TOOL FOR USE IN EXPANDING A CANNULA



(57) Abstract: A surgical tool (112, 410) for use in expanding a cannula (10, 150, 250) includes a first leg (114, 414) having a first end (118, 418) engageable with an inner surface (70, 212, 322) of the cannula. A second leg (114, 414) is connected with the first leg (114, 414). The second leg (114, 414) has a second end (118, 418) engageable with the inner surface (70, 212, 322) of the cannula (10, 150, 250). The first and second ends (118, 418) are movable away from each other to apply a radially outwardly directed force to the inner surface (70, 212, 322) of the cannula (10, 150, 250) and cause expansion of the cannula.

WO 03/007783 A2

WO 03/007783 A2



European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

 without international search report and to be republished upon receipt of that report

SURGICAL TOOL FOR USE IN EXPANDING A CANNULA

Cross-Reference to Related Application

This application is a continuation-in-part of co-pending U.S. Patent Application No. 09/772,605, filed on January 30, 2001 which is a continuation-in-part of U.S. Patent Application Serial No. 09/137,335, filed August 20, 1998, now U.S. Patent No. 6,187,000, issued February 13, 2001.

5

Field of the Invention

The present invention relates to a cannula for receiving surgical instruments for performing a surgical procedure on a body, and more specifically, to a surgical tool for use in expanding the cannula.

Background of the Invention

15 Endoscopic surgical techniques allow a surgical procedure to be performed on a patient's body through a relatively small incision in the body and with a

5

10

15

20

-2-

limited amount of body tissue disruption. Endoscopic surgery typically utilizes a tubular structure known as a cannula which is inserted into a small incision in the body. The cannula holds the incision open and serves as a conduit extending between the exterior of the body and the local area inside the body where the surgery is to be performed.

Due to the relatively small size of the passage into the body which is defined by the cannula, certain surgical procedures, such as posterior disectomies and procedures using steerable surgical instruments, have been difficult to perform using endoscopic techniques.

Summary of the Invention

The present invention is a surgical tool for use in expanding a cannula. The cannula has an inner surface defining a passage through the cannula for receiving surgical instruments. The surgical tool includes a first leg having a first end engageable with the inner surface of the cannula. A second leg is connected with the first leg. The second leg has a second end engageable with the inner surface of the cannula. The first and second ends are movable away from each other to apply a radially outwardly directed

5

-3-

force to the inner surface of the cannula and cause expansion of the cannula.

Brief Description of the Drawings

The foregoing and other features of the present invention will become apparent to one skilled in the art to which the present invention relates upon consideration of the following description of the invention with reference to the accompanying drawings, wherein:

- Fig. 1 is an exploded perspective view of a surgical cannula with a surgical tool constructed in accordance with a first embodiment of the present invention, the cannula being shown in an expanded condition;
- Fig. 2 is a perspective view of the cannula of Fig. 1 with parts removed for clarity, the cannula being shown in a contracted condition;
 - Fig. 3 is a schematic end view showing the cannula of Fig. 1 in the expanded condition;
- 20 Fig. 4 is a rollout view of a part of the cannula of Fig. 1;
 - Fig. 5 is a schematic sectional view of the cannula of Fig. 1 during a surgical procedure;

-4-

Fig. 6 is a perspective view of a part of another embodiment of a surgical cannula, the cannula being shown in an expanded condition;

Fig. 7 is a perspective view of the part of the cannula of Fig. 6, the cannula being shown in a contracted condition;

5

10

15

20

Fig. 8 is a perspective view of a part of another embodiment of a surgical cannula, the cannula being shown in an expanded condition;

Fig. 9 is a sectional view of a portion of the cannula of Fig. 8 showing a rivet connecting a first tubular portion to a second tubular portion; and

Fig. 10 is a perspective view of a surgical tool constructed in accordance with a second embodiment of the present invention.

Description of the Invention

The present invention is directed to a surgical tool for use in expanding a cannula for performing a surgical procedure on the body of a patient. The present invention is applicable to a variety of surgical procedures in which endoscopic surgical techniques are used.

Fig. 1 illustrates a cannula 10. The cannula 10 is a tubular structure 12 centered on an axis 14. The

5

10

15

-5-

tubular structure 12 defines a passage 16 through the cannula 10. Surgical instruments are inserted into the body during endoscopic surgery through the passage 16.

The tubular structure 12 comprises a first tubular portion 20 and a second tubular portion 40 attached to the first tubular portion. The first tubular portion 20 is preferably made of a length of stainless steel tubing, but could alternatively be made of another suitable material such as a radiolucent material. The first tubular portion 20 has a proximal end 22 and a distal end 24. Parallel cylindrical inner and outer surfaces 26 and 28, respectively, extend between the ends 22, 24 of the first tubular portion 20. The inner surface 26 defines a first passage portion 30 of the passage 16 through the cannula 10. The first passage portion 30 has a diameter D1 which is preferably in the range from 10 mm to 25 mm or approximately 0.4 inches to approximately 1.0 inches.

20 The second tubular portion 40 of the tubular structure 12 is attached to the distal end 24 of the first tubular portion 20. The second tubular portion is preferably made from stainless steel, but could

5

10

15

20

-6-

alternatively be made from another suitable material such as a radiolucent material.

As best seen in the rollout view of Fig. 4, the second tubular portion 40 comprises an arcuate segment 42 of sheet stock. The arcuate segment 42 includes first and second arcuate edges 44 and 46, respectively, and first and second planar edges 48 and 50, respectively. The first and second planar edges 48 and 50 are rolled in an overlapping manner to form the tubular configuration of the second tubular portion 40.

When the second tubular portion 40 has been rolled into its tubular configuration, the first and second arcuate edges 44 and 46 define oppositely disposed first and second ends 60 and 62 (Figs. 1 and 2), respectively, of the second tubular portion. The first and second ends 60 and 62 are connected by a central portion 64. The first end 60 of the second tubular portion 40 is attached to the distal end 24 of the first tubular portion 20 by a single suitable fastener, such as a rivet 66. The rivet 66 extends through two aligned apertures 68 (Fig. 4) at the first end 60 of the second tubular portion 40. The first end 60 of

-7-

second tubular portion 40 is pivotable about the rivet 66.

5

10

15

20

The second tubular portion 40 includes parallel inner and outer surfaces 70 and 72 (Figs. 1 and 2), respectively, extending between the first and second ends 60 and 62. The inner surface 70 defines a second passage portion 74 of the passage 16 through the cannula 10 which extends as a continuation of the first passage portion 30 in the first tubular portion 20.

An arcuate slot 80 is formed in the second tubular portion 40 and extends between the inner and outer surfaces 70 and 72 of the second tubular portion. The arcuate slot 80 extends along a curvilinear path in the central portion 64 of the second tubular portion 40 toward the second end 60 of the second tubular portion. The arcuate slot 80 has a first terminal end 82 located in the central portion 64 of the second tubular portion 40. A second terminal end 84 of the arcuate slot 80 is located adjacent the intersection of the second arcuate edge 46 and the first planar edge 48 of the arcuate segment 42.

A suitable guide member, such as guide pin 90, is attached to the inner surface 70 of the second tubular portion 40 adjacent the intersection of the second

5

10

15

20

-8-

arcuate edge 46 and the second planar edge 50. In the tubular configuration of the second tubular portion 40, the guide pin 90 is located in the arcuate slot 80 and is movable along the curvilinear path of the arcuate slot. A washer 92 is secured to an inner end of the guide pin 90 to retain the guide pin in the arcuate slot 80.

The second tubular portion 40 of the tubular structure 12 is expandable from a contracted condition shown in Fig. 2 to an expanded condition shown in Fig. 1. In the contracted condition, the guide pin 90 is located in the first terminal end 82 of the arcuate slot 80 in the second tubular portion 40 and the second passage portion 74 defined by the second tubular portion is cylindrical in shape. The second passage 74 has a generally constant diameter D2 (Figs. 2 and 3) which is approximately equal to the diameter D1 of the first tubular portion 20. Thus, the cross-sectional area of the second passage portion 74 at the second end 62 of the second tubular portion 40, which is a function of the diameter D2, is approximately the same as the cross-sectional area at the first end 60 of the second tubular portion and is approximately the same as

-9-

the cross-sectional area of the first passage portion 30 in the first tubular portion 20.

5

10

15

20

In the expanded condition, the guide pin 90 is located in the second terminal end 84 of the arcuate slot 80 in the second tubular portion 40 and the second tubular portion has a conical configuration. At the second end 62 of the second tubular portion 40, the second passage portion 74 has a diameter D3 (Fig. 3) which is larger than the diameter D2 of the second passage portion at the first end 60. Preferably, the diameter D3 of the second passage portion 74 at the second end 62 of the second tubular portion is 40% to 90% greater than the diameter D2 of the second passage portion at the first end 60. Thus, in the expanded condition, the cross-sectional area of the second passage portion 74 at the second end 62 of the second tubular portion 40, which is a function of the diameter D3, is greater than the cross-sectional area of the second passage portion at the first end 60 of the second tubular portion. Although the cross-sectional area at the second end 62 is shown as being circular in Fig. 3, it is contemplated that the cross-sectional area at the second end 62 could be any shape, such as oval shaped.

5

10

15

20

-10-

The cannula 10 includes an outer layer 100

(Fig. 1) for maintaining the second tubular portion 40 of the cannula in the contracted condition. It is contemplated that other suitable means for maintaining the second tubular portion 40 in the contracted condition could be employed. In accordance with a preferred embodiment of the present invention, the outer layer 100 comprises a section of plastic tubing 102 which is heat shrunk over both the first and second tubular portions 20 and 40 to hold the second tubular portion in the contracted condition.

In addition, a loop of polyester string 104 for tearing the heat shrink tubing 102 is wrapped around the heat shrink tubing so that it extends both underneath and on top of the tubing. An outer end 106 of the string 104 extends beyond the tubing 102.

The cannula 10 further includes an actuatable device 110 for expanding the second tubular portion 40 from the contracted condition to the expanded condition. In accordance with a first embodiment of the present invention, the actuatable device 110 comprises a manually operated expansion tool 112. The expansion tool 112 resembles a common pair of scissors and has a pair of legs 114 pivotally connected to one

5

10

15

20

-11-

another. The expansion tool 112 includes a frustoconical end section 116 formed by a pair of frustoconical halves 118. Each of the frustoconical halves 118 extends from a respective one of the legs 114 of the expansion tool 112. It is contemplated that other suitable means for expanding the second tubular portion 40 toward the expanded condition could be employed, such as an inflatable balloon (not shown).

During an endoscopic surgical procedure, the cannula 10 is inserted through an incision into the body of a patient in the contracted condition. The cannula 10 is inserted through the incision using step dilation. The second tubular portion 40 is inserted inside the body. The first tubular portion 20 is inserted into the incision so that the first tubular portion extends from an exterior of the body to inside the body.

The outer end 106 of the string 104 is then manually pulled on by the surgeon. Pulling on the string 104 tears the heat shrink tubing 102. With the heat shrink tubing 102 torn, the second tubular portion 40 of the cannula 10 is thereby released for expansion toward the expanded condition.

1.5

5

10

15

20

-12-

Next, the expansion tool 112 is inserted into the passage 16 in the cannula 10 until the frustoconical end section 114 is located at the second end 62 of the second tubular portion 40. The legs 114 of the expansion tool 112 are manually separated, causing the frustoconical halves 118 to separate also. As the halves 118 separate, a radially outwardly directed force is exerted on the inner surface 70 of the second tubular portion 40 by the halves 118, causing the second tubular portion to expand toward the expanded condition.

Under the force of the expanding expansion tool 112, the guide pin 90 slides from the first terminal end 82 of the arcuate slot 80 to the second terminal end 84 of the arcuate slot to permit the expansion of the second tubular portion 40. The expansion tool 112 can be rotated about the axis 14 to ensure that the second tubular portion 40 of the cannula 10 is completely expanded to the expanded condition. The expansion tool 112 is then collapsed and removed so that one or more surgical instruments (indicated schematically at 120 in Fig. 5) can be received through the cannula 10 and inserted into a patient's body 130.

5

10

15

20

-13-

The expandable second tubular portion 40 of the cannula 10 provides a significantly larger working area for the surgeon inside the body 130 within the confines of the cannula. As a result, the simultaneous use of a number of endoscopic surgical instruments, including but not limited to steerable instruments, shavers, dissectors, scissors, forceps, retractors, dilators, and endoscopes, is made possible by the expandable cannula 10.

A surgical tool 410 constructed according to a second embodiment of the present invention is illustrated in Fig. 10. The surgical tool 410 resembles a common pair of scissors and has a pair of legs 414 pivotally connected to each other by a pivot connection 416. Each of the legs 414 has an end 418 with a tapered outer surface 420. Each of the ends 418 has a generally U-shaped cross-section with outer surfaces 422 and 424. The surfaces 422 and 424 extend generally parallel to each other and transverse to the tapered surface 420.

The legs 414 have handles 430 opposite the ends 418. The handles 430 may be grasped by a surgeon to move the ends 418 away from each other. The handles 430 are moved toward each other to move the

-14-

ends 418 away from each other. Each of the legs 414 has a stop 434 that engages the other leg to limit the movement of the ends 418 away from each other.

The expansion tool 410 is inserted into the passage 16 in the cannula 10 until the ends 418 are 5 located at the second end 62 of the second tubular portion 40. The legs 418 of the expansion tool 410 are manually separated by moving the handles 430 toward each other. As the handles 430 are moved toward each other, the ends 418 separate. As the ends 418 10 separate, a radially outwardly directed force is exerted on the inner surface 70 of the second tubular portion 40 by the ends 418, causing the second tubular portion to expand toward the expanded condition. Under the force of the expanding expansion tool 410, the 15 guide pin 90 slides from the first terminal end 82 of the arcuate slot 80 toward the second terminal end 84 of the arcuate slot to permit the expansion of the second tubular portion 40. The expansion tool 410 can be rotated about the axis 14 to ensure that the second 20 tubular portion 40 of the cannula 10 is completely expanded to the expanded condition. The expansion tool 410 is then collapsed and removed so that one or

5

-15-

more surgical instruments can be received through the cannula 10 and inserted into a patient's body.

A cannula 150 constructed according to another embodiment is illustrated in Figs. 6-7. The cannula 150 includes a tubular structure 152 centered on an axis 154. The tubular structure 152 defines a passage 156 through the cannula 150. Surgical instruments are inserted into the body during endoscopic surgery through the passage 156.

The tubular structure 152 (Fig. 6) comprises a 10 first tubular portion 160 and a second tubular portion 180 attached to the first tubular portion. first tubular portion 160 is preferably made of a length of stainless steel tubing, but could alternatively be made of another suitable material, 15 such as a radiolucent material. The first tubular portion 160 has a proximal end 162 and a distal end 164. Parallel cylindrical inner and outer surfaces 166 and 168 extend between the ends 162, 164 of the first tubular portion 160. The first tubular 20 portion 160 has a thickness measured perpendicular to the surfaces 166 and 168 in the range of .02 inches to .04 inches or approximately 0.5 mm to approximately 1.0 mm.

5

10

15

20

-16-

The inner surface 166 defines a first passage portion 170 of the passage 156 through the cannula 150. The first passage portion 170 has a diameter d1 which is preferably in the range from 10 mm to 25 mm or approximately 0.4 inches to approximately 1.0 inches. The inner surface 166 has a non-reflective coating 174. The non-reflective coating 174 reduces glare on any video image produced by an endoscope inserted through the passage 156. It is contemplated that the inner surface 166 may not have the coating 174.

The second tubular portion 180 (Fig. 6) of the tubular structure 152 is attached to the distal end 164 of the first tubular portion 160. The second tubular portion 180 is preferably made from stainless steel, but could alternatively be made from another suitable material, such as a radiolucent material.

The second tubular portion 180 includes an arcuate segment 182 of sheet stock. The arcuate segment 182 includes first and second arcuate edges 184 and 186. The arcuate segment 182 also includes a first planar edge 188 and a second planar edge extending between the arcuate edges 184 and 186, which is not shown in Fig. 6. The first and second planar edges are rolled

-17-

in an overlapping manner to form the tubular configuration of the second tubular portion 180.

5

10

15

20

When the second tubular portion 180 has been rolled into its tubular configuration, the first and second arcuate edges 184 and 186 define oppositely disposed first and second ends 200 and 202 of the second tubular portion. The first and second ends 200 and 202 are connected by a central portion 204. The first end 200 of the second tubular portion 180 is attached to the distal end 164 of the first tubular portion 160 by a suitable fastener, such as a screw 206 and nut 208 threaded on the screw. It is contemplated that the second tubular portion 180 could be connected to the first tubular portion 160 by a rivet. screw 206 extends through two aligned apertures 240 at the first end 200 of the second tubular portion 180. The first end 200 of the second tubular portion 180 is pivotable about the screw 206.

The second tubular portion 180 includes parallel inner and outer surfaces 212 and 214 extending between the first and second ends 200 and 202. The inner surface 212 defines a second passage portion 216 of the passage 156 through the cannula 150 which extends as a continuation of the first passage portion 170 in the

-18-

first tubular portion 160. The second tubular portion 180 has a thickness measured perpendicular to the surfaces 212 and 214 in the range of .003 inches to .006 inches or approximately .075 mm to approximately .15 mm. The inner surface 212 has a non-reflective coating 218. The non-reflective coating 218 reduces glare on any video image produced by an endoscope inserted through the passage 156. It is contemplated that the inner surface 212 may not have the coating 218.

5

10

15

20

An arcuate slot 220 (Fig. 6) is formed in the second tubular portion 180 and extends between the inner and outer surfaces 212 and 214 of the second tubular portion. The arcuate slot 220 extends along a curvilinear path in the central portion 204 of the second tubular portion 180 toward the end 184 of the second tubular portion. The arcuate slot 220 has a first terminal end (not shown) located in the central portion 204 of the second tubular portion 180. A second terminal end 224 of the arcuate slot 220 is located adjacent the intersection of the second arcuate edge 186 and the planar edge 188 of the arcuate segment 182.

-19-

A guide member or screw 230 is attached to the inner surface 212 of the second tubular portion 180 adjacent the intersection of the second arcuate edge 186 and the planar edge (not shown). It is contemplated that a guide pin could be used instead of the screw 230. In the tubular configuration of the second tubular portion 180, the guide member 230 is located in the arcuate slot 220 and is movable along the curvilinear path of the arcuate slot.

5

10 The second tubular portion 180 of the tubular structure 152 is expandable from a contracted condition, shown in Fig. 7, to an expanded condition, shown in Fig. 6. In the contracted condition (Fig. 7), the guide member 230 is located in the first terminal end (not shown) of the arcuate slot 220 in the second 15 tubular portion 180 and the second passage portion 216 defined by the second tubular portion is cylindrical in shape. The second passage 216 has a generally constant diameter d2 which is approximately equal to the diameter d1 of the first tubular portion 160. Thus, 20 the cross-sectional area of the second passage portion 216 at the second end 202 of the second tubular portion 180, which is a function of the diameter d2, is approximately the same as the cross-sectional area at

-20-

the first end 200 of the second tubular portion and is approximately the same as the cross-sectional area of the first passage portion 170 in the first tubular portion 160.

5 In the expanded condition (Fig. 6), the guide member 230 is located in the second terminal end 224 of the arcuate slot 220 in the second tubular portion 180 and the second tubular portion has a conical configuration. At the second end 202 of the second 10 tubular portion 180, the second passage portion 216 has a diameter d3 which is larger than the diameter d2 of the second passage portion at the first end 200. Preferably, the diameter d3 of the second passage portion 216 at the second end 202 of the second tubular 15 portion is 40% to 90% greater than the diameter d2 of the second passage portion at the first end 200. Thus, in the expanded condition, the cross-sectional area of the second passage portion 216 at the second end 202 of the second tubular portion 180, which is function of 20 the diameter d3, is greater than the cross-sectional area of the second passage portion at the first end 200 of the second tubular portion. Although the cross-sectional area at the second end 202 is shown as being circular in Fig. 6, it is contemplated that the

5

10

15

20

-21-

cross-sectional area at the second end 202 could be any shape, such as oval shaped.

The cannula 150 includes an outer member (not shown) for maintaining the second tubular portion 180 of the cannula in the contracted condition. It is contemplated that other suitable means for maintaining the second tubular portion 180 in the contracted condition could be employed. In accordance with the present invention, the outer member may be similar to the layer 100 shown in Fig. 1 and include a section of plastic tubing which is heat shrunk over both the first and second tubular portions 160 and 180 to hold the second tubular portion in the contracted condition. addition, a loop of polyester string (not shown) for tearing the heat shrink tubing is wrapped around the heat shrink tubing so that it extends both underneath and on top of the tubing. An outer end of the string extends beyond the tubing.

During an endoscopic surgical procedure, the cannula 150 is inserted through an incision into the body of a patient in the contracted condition. The cannula 150 is inserted through the incision using step dilation. The second tubular portion 180 is inserted inside the body. The first tubular portion 160 is

5

-22-

inserted into the incision so that the first tubular portion extends from an exterior of the body to inside the body.

The outer end of the string is then manually pulled on by the surgeon. Pulling on the string tears the heat shrink tubing. With the heat shrink tubing torn, the second tubular portion 180 of the cannula 150 is thereby released for expansion toward the expanded condition.

10 Next, one of the expansion tools 112 and 410, shown in Figs. 1 and 10, is inserted into the passage 156 in the cannula 150 until the frustoconical end section 118 or 418 is located at the second end 202 of the second tubular portion 180. The legs 114 or 414 15 of the expansion tool 112 or 410 are manually separated, causing the frustoconical halves 118 or ends 418 to separate also. As the halves 118 or ends 418 separate, a radially outwardly directed force is exerted on the inner surface 212 of the second 20 tubular portion 180 by the halves 118 or ends 418, causing the second tubular portion to expand toward the expanded condition. Under the force of the expanding expansion tool 112 or 410, the guide member 230 slides from the first terminal end of the arcuate slot 220 to

5

10

15

20

-23-

the second terminal end of the arcuate slot to permit
the expansion of the second tubular portion 180. The
expansion tool 112 or 410 can be rotated about the
axis 154 to ensure that the second tubular portion 180
of the cannula 150 is completely expanded to the
expanded condition. The expansion tool 112 or 410 is
then collapsed and removed so that one or more surgical
instruments can be received through the cannula 150 and
inserted into a patient's body.

The expandable second tubular portion 180 of the cannula 150 provides a significantly larger working area for the surgeon inside the body within the confines of the cannula. As a result, the simultaneous use of a number of endoscopic surgical instruments, including but not limited to steerable instruments, shavers, dissectors, scissors, forceps, retractors, dilators, and endoscopes, is made possible by the expandable cannula 150.

A cannula 250 constructed according to another embodiment is illustrated in Figs. 8-9. In the embodiment of the cannula 150 illustrated in Figs. 6-7 the tubular portions 160 and 180 are connected by a screw 206 and nut 208 and the guide member is a screw 230. In the embodiment of the cannula 250

5

10

15

-24-

illustrated in Figs. 8-9 the tubular portions are connected by a rivet and the guide member is a rivet. The cannula 250 is generally similar to the cannula 150 shown in Figs. 6-7. Accordingly, only the rivets will be described in detail.

The cannula 250 (Fig. 8) includes a tubular structure 252 centered on an axis 254. The tubular structure 252 defines a passage 256 through the cannula 250. The tubular structure 252 includes a first tubular portion 260 and a second tubular portion 280 attached to the first tubular portion. The first tubular portion 260 has a proximal end 262 and a distal end 264. Parallel cylindrical inner and outer surfaces 266 and 268 extend between the ends 262, 264 of the first tubular portion 260. The inner surface 266 defines a first passage portion 270 of the passage 256 through the cannula 250. The inner surface 266 could have a non-reflective coating (not shown).

The second tubular portion 280 (Fig. 8) of the tubular structure 252 is attached to the distal end 264 of the first tubular portion 260. The second tubular portion 280 includes an arcuate segment 282 of sheet stock. The arcuate segment 282 includes first and

5

10

15

20

second arcuate edges 284 and 286. The arcuate segment 282 also includes a first planar edge 288 and a second planar edge extending between the arcuate edges 284 and 286, which is not shown in Fig. 8. The first and second planar edges are rolled in an overlapping manner to form the tubular configuration of the second tubular portion 280.

When the second tubular portion 280 has been rolled into its tubular configuration, the first and second arcuate edges 284 and 286 define oppositely disposed first and second ends 300 and 302 of the second tubular portion. The first and second ends 300 and 302 are connected by a central portion 304. The first end 300 of the second tubular portion 280 is attached to the distal end 264 of the first tubular portion 260 by a rivet 306. The rivet 306 extends through two aligned apertures 340 at the first end 300 of the second tubular portion 280. The first end 300 of the second tubular portion 280 is pivotable about the rivet 306.

The rivet 306 (Figs. 8 and 9) has a first portion 308 and a second portion 310. The first portion 308 has a shaft 312 extending from a head 314. The shaft 312 extends through the apertures 340 in the

5

10

15

20

-26-

tubular portion 280 and the head engages the inner surface 266 of the first tubular portion 260. A cylindrical opening 316 extends through the shaft 312 and the head 314.

The second portion 310 of the rivet 306 has a shaft 318 extending from a head 320. The shaft 318 extends into the opening 316 in the first portion 308 of the rivet 306 and the head 320 engages the second tubular portion 280. The shaft 318 of the second portion 310 extends into the opening 316 in the first portion 308 to connect the first and second portions of the rivet 306 and pivotally connect the second tubular portion 280 to the first tubular portion 260.

The second tubular portion 280 (Fig. 8) includes parallel inner and outer surfaces 322 and 324 extending between the first and second ends 300 and 302. The inner surface 322 defines a second passage portion 326 of the passage 256 through the cannula 250 which extends as a continuation of the first passage portion 270 in the first tubular portion 260. The inner surface 322 could have a non-reflective coating (not shown).

An arcuate slot 330 is formed in the second tubular portion 280 and extends between the inner and

5

10

15

20

outer surfaces 322 and 324 of the second tubular portion. The arcuate slot 330 extends along a curvilinear path in the central portion 304 of the second tubular portion 280 toward the end 284 of the second tubular portion. The arcuate slot 330 has a first terminal end (not shown) located in the central portion 304 of the second tubular portion 280. A second terminal end 334 of the arcuate slot 330 is located adjacent the intersection of the second arcuate edge 286 and the planar edge 288 of the arcuate segment 282.

A rivet 336 is attached to the inner surface 322 of the second tubular portion 280 adjacent the intersection of the second arcuate edge 286 and the planar edge (not shown). It is contemplated that a guide pin could be used instead of the rivet 336. In the tubular configuration of the second tubular portion 280, the rivet 336 is located in the arcuate slot 330 and is movable along the curvilinear path of the arcuate slot. The rivet 336 extends through a washer 338 to retain the rivet in the arcuate slot 330.

The rivet 336 is generally similar to the rivet 306 and, therefore, will not be described in detail. The rivet 336 has a first portion 342 and a

5

10

15

20

-28-

second portion 344. The first portion 342 has a shaft 346 extending from a head 348. The shaft 346 extends through the slot 330 and the head 348 engages the washer 338. A cylindrical opening 350 extends through the shaft 346 and the head 348.

The second portion 344 of the rivet 336 has a shaft 352 extending from a head 354. The shaft 352 extends into the opening 350 in the first portion 342 of the rivet 336 and the head 354 engages the outer surface 324 of the second tubular portion 280. The shaft 352 extends into the opening 350 to connect the first portion 342 of the rivet 336 to the second portion 344.

The second tubular portion 280 of the tubular structure 252 is expandable from a contracted condition to an expanded condition, shown in Fig. 8. In the contracted condition the rivet 336 is located in the first terminal end (not shown) of the arcuate slot 330 in the second tubular portion 280 and the second passage portion 326 defined by the second tubular portion is cylindrical in shape. The second passage portion 326 has a generally constant diameter which is approximately equal to the diameter of the first tubular portion 260. Thus, the cross-sectional area of

5

10

15

-29-

the second passage portion 326 at the second end 302 of the second tubular portion 280 is approximately the same as the cross-sectional area at the first end 300 of the second tubular portion and is approximately the same as the cross-sectional area of the first passage portion 270 in the first tubular portion 260.

In the expanded condition (Fig. 8), the rivet 336 is located in the second terminal end 334 of the arcuate slot 330 in the second tubular portion 280 and the second tubular portion has a conical configuration. At the second end 302 of the second tubular portion 280, the second passage portion 326 has a diameter which is larger than the diameter of the second passage portion at the first end 300. Thus, in the expanded condition, the cross-sectional area of the second passage portion 326 at the second end 302 of the second tubular portion 280 is greater than the cross-sectional area of the second passage portion at the first end 300 of the second tubular portion.

Although the cross-sectional area at the second end 302 is shown as being circular in Fig. 8, it is contemplated that the cross-sectional area at the second end 302 could be any shape, such as oval shaped.

5

-30-

During an endoscopic surgical procedure, the cannula 250 is inserted through an incision into the body of a patient in the contracted condition. The cannula 250 is inserted through the incision using step dilation. The second tubular portion 280 is inserted inside the body. The first tubular portion 260 is inserted into the incision so that the first tubular portion extends from an exterior of the body to inside the body.

Heat shrink tubing is torn from the cannula 250 by 10 the surgeon. With the heat shrink tubing torn, the second tubular portion 280 of the cannula 250 is thereby released for expansion toward the expanded condition. Next, one of the expansion tools 112, 410 shown in Figs. 1 and 10, is inserted into the 15 passage 256 in the cannula 250 until the frustoconical end section 118 or 418 is located at the second end 302 of the second tubular portion 280. The legs 114 or 414 of the expansion tool 112 or 410 are manually separated, causing the frustoconical halves 118 or 20 ends 418 to separate also. As the halves 118 or ends 418 separate, a radially outwardly directed force is exerted on the inner surface 312 of the second tubular portion 280 by the halves 118 or ends 418,

5

10

15

-31-

causing the second tubular portion to expand toward the expanded condition. Under the force of the expanding expansion tool 112 or 410, the rivet 336 slides from the first terminal end of the arcuate slot 330 to the second terminal end 334 of the arcuate slot to permit the expansion of the second tubular portion 280. The expansion tool 112 or 410 is then collapsed and removed so that one or more surgical instruments can be received through the cannula 250 and inserted into a patient's body.

The expandable second tubular portion 280 of the cannula 250 provides a significantly larger working area for the surgeon inside the body within the confines of the cannula. As a result, the simultaneous use of a number of endoscopic surgical instruments, including but not limited to steerable instruments, shavers, dissectors, scissors, forceps, retractors, dilators, and endoscopes, is made possible by the expandable cannula 250.

It is contemplated that the cannula 10, 150, and/or the cannula 250 described herein could be the centerpiece of an endoscopic surgical kit with the surgical tool 112 and/or 410 which would include an





11 Publication number:

0 528 562 A2

(2)

EUROPEAN PATENT APPLICATION

21 Application number: 92306935.5

(51) Int. CI.5: A61B 17/56

② Date of filing: 30.07.92

(3) Priority: 15.08.91 US 745474

Date of publication of application: 24.02.93 Bulletin 93/08

Designated Contracting States:
 AT BE CH DE DK ES FR GB IT LI MC NL PT
 SE

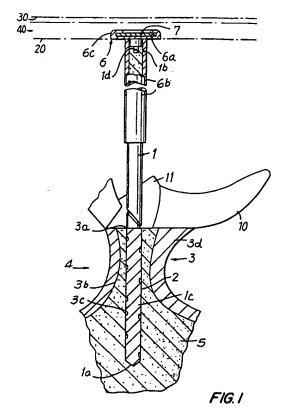
Applicant: SMITH & NEPHEW DYONICS INC 160 Dascomb Road Andover, Massachusetts 01810(US)

Inventor: Kambin, Parvis239 Chester RoadDevon, Pennsylvania 19333(US)

Representative: W.P. Thompson & Co. Coopers Building, Church Street Liverpool L1 3AB (GB)

- Pedicle screw and percutaneous fixation of vertebrae.
- There is additionally described a method for percutaneous fixation of a pair of vertebrae of a patient, which comprises posterolaterally entering the back of a patient percutaneously with a plurality of pedicle screws (1), screwing each pedicle screw (1) into the medullary canal (2) of the pedicles (3) of adjacent thoracic and/or lumbar vertebrae or the pedicles of the L5 and S1 vertebrae, to a position where the proximal end (1b) thereof lies adjacent the fascia (20) of the patient; inserting pedicle screw linkages (6, 7) under the skin of the back of the patient and detachably securing the linkage means to the proximal ends (1b) of the screws (1) on the same side of the spinous processes of the vertebrae to restrict relative movement between the vertebrae.

There is disclosed a pedicle screw (1) for percutaneous internal fixation of vertebrae, comprising proximal and distal ends (1b, 1a) and sized to enable the distal end (1a) to be screwed into the medullary canal (2) of a pedicle (3) of a vertebrae (4) with the proximal end (1b) thereof lying adjacent the fascia (20) of a patient. There is also disclosed a kit for percutaneous fixation of vertebrae of a patient, comprising a plurality of pedicle screws (1) of different sizes, yet of a size to enable the distal end (1a) of each screw (1) to be screwed into the medullary canal (2) of a pedicle (3) of a vertebra (4) with the proximal end (16) thereof lying adjacent the fascia (20) of a patient.



20

25

30

35

40

The present invention relates to percutaneous interbody fusion with subcutaneous internal fixators. More particularly, the present invention relates to percutaneous fixation of lumbar vertebrae by means of a minimally invasive technique.

1

The use of internal fixators for fixation of unstable fractures of the vertebrae is known. Also known is a system for internal fixation of vertebrae after the removal of one or more intervertebral discs. External fixation systems for the stabilization of thoracic and lumbar fractures have also been proposed.

The use of existing internal fixators requires a large incision in the back and dissection of the paraspinal muscles, which is a highly invasive procedure. If the internal fixators must be removed, a second major invasive procedure is required. Moreover, patients undergoing an internal fixation procedure require a lengthy rehabilitation, including reconditioning of the muscles.

The use of external fixators requires the patient to carry a fixation assembly on the surface of the back, which is difficult from a physical and psychological point of view for a majority of patients. Moreover, the rehabilitation of paraplegic patients with external fixators has proven to be difficult.

In addition, external fixators have portals in the skin which become sites for infection.

There is thus a need in the art for skeletal fixation that can be performed with minimal injury to the muscular ligamentous structures.

There is also a need in the art for a method of skeletal fixation whereby the extraction of the fixators is accomplished with minimal surgical intervention.

There is a further need in the art for a method of skeletal fixation which is acceptable both psychologically and cosmetically, and which minimizes infection.

The present invention provides a method for percutaneous fixation of vertebrae of a patient, which comprises posterolaterally entering the back of a patient percutaneously with a plurality of pedicle screws, screwing each pedicle screw into the medullary canal of the pedicles of adjacent thoracic and/or lumbar vertebrae or the pedicles of the L5 and S1 vertebrae, to a position where the proximal ends of the screws lie adjacent the fascia of the patient; inserting first and second pedicle screw linkage means under the skin of the back of the patient and detachably securing the linkage means to the proximal ends of said screws on the same side of the spinous processes of said vertebrae to restrict relative movement between the vertebrae.

As can be seen, the method of the present invention requires only a small incision to enable the surgeon to link the pedicle screws together. The fixators are located internally, thereby avoiding

the disadvantages of external fixation. Since the subcutaneous fixators used in the present invention may be removed routinely after a period of rehabilitation, such as from 10 to 12 weeks, future MRI and CT visualization of the spinal canal and the lateral recesses are then possible. In contrast, the permanent implantation of internal fixators prevents the use of MRI and CT visualizations.

The method may be used to achieve a cosmetically desirable effect, e.g. by improving the posture and/or look of the patient.

The present invention further provides a kit for percutaneous fixation of vertebrae of a patient, comprising a plurality of pedicle screws of different sizes, yet of a size to enable the distal end of each screw to be screwed into the medullary canal of each pedicle of a vertebra with the proximal end thereof lying adjacent the fascia of a patient. The kit may include a plurality of linkage means proportioned to lie under the skin of the patient and operable to detachably link together the proximal ends of the pedicle screws inserted into the pedicles of the vertebrae.

The invention further comprises a pedicle screw for percutaneous internal fixation of vertebrae, comprising proximal and distal ends and sized to enable the distal end to be screwed into the medullary canal of a pedicle of a vertebrae with the proximal end thereof lying adjacent the fascia of a patient.

The method of the invention preferably comprises one or more of the following:

- (i) the distal portion of the pedicle screw carries a bone screw thread;
- (ii) the proximal portion of the pedicle screw carries means engageable with a pedicle screw driver;
- (iii) the pedicle screws in the kit are of different diameters;
- (iv) the pedicle screws in the kit have distal portions carrying bone screw threads of different lengths;
 - (v) the kit includes a plurality of linkage means proportioned to lie under the skin of the patient and operable to detachably link together the proximal ends of said pedicle screws inserted into the pedicles of said vertebrae;
 - (vi) said linkage means comprises a plurality of beam members and a plurality of adaptor means for detachably securing said beam members thereto, said adaptor means being detachably fastenable to said proximal ends of said pedicle screws:
 - (vii) said adaptor means comprise a slotted cap and a tubular body extending therefrom, said slot lying in a plane perpendicular to said tubular body, each of the slots being proportioned to receive a beam member, some of the caps

15

20

having a slot open at both ends and others having a slot open at one end and closed at the other:

(viii) said vertebrae are aligned before insertion of said beam members, said beam members being locked in place to maintain said alignment;

(ix) the slot of one of said caps is open at both ends while the slot of the other said cap is open at one end and closed at the other, said beam member being slid through said slot of said one cap into said slot of said other cap;

(x) each said opening is formed by locating the position of said opening fluoroscopically, posterolaterally introducing a guide wire through the skin of the patient's back and advancing said guide wire to said location and into said cortical bone at said junction; sliding a cannulated obturator over said guide wire and advancing said obturator to said junction; sliding an access cannula over said obturator and advancing said cannula to said juncture; removing said obturator; forming said opening with a pedicle cannulated drill means inserted in said access cannula over said guide wire and thereafter removing said guide wire and said drill means;

(xi) a blunt end member is inserted in said access cannula and advanced into said medullary canal to crush cancellous bone therein and thereby form said medullary canal bore;

(xii) said pedicle screw is screwed into said medullary canal bore via said access cannula, and said access cannula is removed;

(xiii) said pedicle screw has at its proximal end means for engaging a pedicle screw driver, said driver being introduced into said access cannula, said pedicle screw being screwed into said medullary canal bore by said screw driver;

(xiv) said adaptor is fastened onto said proximal end of said pedicle screw;

(xv) said adaptor is screwed in place onto said proximal end of said pedicle screw;

(xvi) said adaptor cap is substantially flat and is fastened flush against the lumbar fascia of the patient;

(xvii) the intervertebral disc between said vertebrae is removed and bone grafts are implaced before said beam members are inserted into each pair of associated adaptors and locked into place;

(xix) said beam member is a plate or rod;

(xx) said pedicle screws are implanted in the pedicles of adjacent thoracic vertebrae;

(xxi) said pedicle screws are implanted in the pedicles of adjacent lumbar vertebrae;

(xxii) said pedicle screws are implanted in the pedicles of adjacent thoracic and lumbar vertebrae;

(xxiii) said pedicle screws are implanted in the pedicles of the L5 and S1 vertebrae.

The present invention is illustrated by way of example in terms of its preferred embodiments in the accompanying drawings, in which:

Fig.1 is a schematic view, partly in section in enlarged scale, of one of the pedicles of a lumbar vertebra into which has been inserted a pedicle screw with a beam member detachably linked to the pedicle screw:

Fig. 2 is a schematic view, in enlarged scale, showing the subcutaneous fixation system of the present invention implanted in a patient;

Figs. 3-8 are elevational views of various instruments used to perform the surgical procedure of the present invention;

Fig. 9 is a plan view of a kit for carrying out the method of the present invention;

Fig. 10 is an elevational view of a tool used to carry out the method of the present invention; and

Fig. 11 is a view in perspective of an alternative embodiment of the present invention.

Fig. 1 schematically shows a pedicle screw 1 inserted into the medullary canal 2 of the pedicle 3 of a lumbar vertebra 4 of a patient. The distal end 1a of the pedicle screw 1 extends into the body 5 of the vertebra 4, while the proximal end 1b lies adjacent to the lumbar fascia 20 (shown in phantom line). Fastened to the proximal end 1b of pedicle screw 1 is an adaptor 6 having a slot 6a therein for receiving a beam member 7, here shown in the form of a plate. Fig. 1 shows the pedicle screw 1 inserted into the pedicle 3 situated to one side of the spinous process (not shown) of the vertebra 4. In the same manner, the pedicle (not shown) lying on the other side of the spinous process is also provided with a pedicle screw and an adaptor. The intervertebral disc to be removed lies between the vertebra 4 shown in Fig. 1 and a lumbar vertebra adjacent thereto (Fig. 2), which is also provided with pedicle screws inserted in the pedicles thereof, adaptors fastened to the proximal ends of the pedicle screws, and a beam member in the same manner as shown in Fig. 1.

Fig. 2 is a schematic view of the assembly of pedicle screws, adaptors and beam members of the invention, as viewed posteriorly with part of the skin 30 and subcutaneous tissue 40 of the patient removed for ease of illustration. Thus, pedicle screws 1 are held in the one pair of the pedicles (not shown) of lumbar vertebra La, while the other pair of pedicle screws 1 is held in the pedicle of vertebra Lb immediately above or below lumbar vertebra La. The intervertebral disc D to be removed is between lumbar vertebra La and Lb as schematically indicated. All of the adaptors 6 are preferably flush against the lumbar fascia 20 as

45

20

25

30

35

shown in Fig. 1. Pedicle screws 1, adaptors 6 and beam members 7 are all made of biocompatible material, suitably stainless steel.

The surgical procedure for percutaneous fixation of lumbar vertebra of the invention may be carried out as follows. The patient is placed prone on a radiolucent table and frame (not shown). The C-arm of a conventional fluoroscope is positioned for anteroposterior visualization of the lumbar vertebrae and the table is tilted away from the C-arm to permit better localization of the pedicles. A cannulated tubular guide 8 (Fig. 3) is maneuvered by hand or by the flexible holder 9 (Fig. 4) having its proximal end 9a secured to the table and carrying at its distal end a ring 9b for holding guide 8. The guide 8 is maneuvered with the holder 9 until the guide 8 is aligned with the longitudinal axis of the pedicle, after which the holder 9 is locked into place. When properly aligned, the guide 8 will appear by fluoroscopy as an opaque circle in the center of the pedicle. A guide wire (not shown), suitably of 2mm outside diameter, is introduced into the guide 8 and is advanced through the skin of the patient's back, posterolaterally toward the pedicle 3. The guide wire is tapped with a mallet into the cortical bone at the junction of the base of the transverse process 10 (Fig. 1) and the proximal articular process 11. After removal of guide 8, a cannulated obturator 11 (Fig. 5) having a lumen 11a is placed over the guide wire and advanced through the skin of the patient's back to the pedicle 3, followed by placing an access cannula 12 (Fig. 6) over the obturator 11, and advancing the cannula 12 to the pedicle 3.

The obturator 11 is then removed, and a cannulated drill 13 having a lumen 13a (Fig. 7) is placed over the guide wire and advanced to the pedicle 3. By manually operating the drill 13, the opening of the cortex of the pedicle is enlarged to form an entrance 3a (Fig. 1) into the medullary canal 3b of the pedicle 3. The cannulated drill 13 is removed and a blunt end pedicle screw probe 14 (Fig. 8) is manually advanced into the medullary canal 3b with a twisting motion, to crush the cancellous bone of the medullary canal 3b thus creating a tunnel or bore 3c (Fig. 1) extending from the pedicle 3 into the vertebral body 5 (Fig. 1). The probe 14 or a blunt end K-wire can be inserted into the bore 3c, the position and length of the probe or K-wire being checked by anteroposterior and lateral fluoroscopy.

If desired by the surgeon, the bore 3c may be tapped to receive the threads 1c of the pedicle screw 1. Alternatively, a self-tapping pedicle screw may be used. Before implanting the pedicle screw 1, the bore 3c may be inspected arthroscopically to make certain that the cortex 3d (Fig. 1) of the pedicle 3 has not been violated; if it has been, the

surgeon may abort the procedure.

The length of the pedicle screw 1 to be used may be determined by the use of a K-wire. Thus, the K-wire can be used to measure the depth of bore 3c, and the distance between the bone and the lumbar fascia 20.

The appropriate pedicle screw 1 is selected from the kit 50 (Fig. 9) containing a plurality of pedicle screws 1, beam members 7 and adaptors 6 in a container 51. The pedicle screws 1 are all of a size to enable the distal end 1a of each screw 1 to be screwed into the medullary canal 3b of the pedicle 3 of a lumber vertebrae with the proximal end 1b thereof lying adjacent the lumbar fascia 20 of a patient, while the beam members 7 are proportioned to lie under the skin 30 of the patient and operate to detachably link together the proximal ends 1b of a pair of pedicle screws 1 (Fig. 2) inserted into the pedicles 3 of the lumbar vertebrae.

Generally, the pedicle screws 1 in kit 50 will be of different lengths and diameters. However, it is contemplated that the kit may contain pedicle screws 1 of different lengths and the same diameters. Moreover, while the beam members 7 may of different lengths, all sized to be received in adaptors 6, some beam members 7 in the kit 51 may be much longer and will be cut to length by the surgeon. Adaptors 6 will comprise adaptors having a slot 6a open at one end and closed at the other, such as the upper adaptors 6 as viewed in Fig. 2, while others will have a slot 6a open at both ends, such as the lower adaptors 6 as viewed in Fig. 2.

The pedicle screw 1 selected is placed into the access cannula 12 and thence into the bore 3c. An allen wrench (not shown) may be inserted into the recess 1d (Fig. 1), to drive the pedicle screw 1 into the bore 3c. However, pedicle screw 1 may be provided with any suitable means for engaging a pedicle screw driver, such as a slot in screw 1 and a corresponding blade for the driver.

After pedicle screw 1 is implanted, an adaptor guide 15 (Fig. 10) having an outside diameter smaller than the inside diameter of the tubular body 6b is inserted through the access cannula 12 so that the projection 15a enters recess 1d (Fig. 1), after which the access cannula 12 is removed. An adaptor 6 is slid over the adaptor guide 15 and is screwed in place over the external threads on the proximal end 1b of screw 1, to the position shown in Fig. 1. All of the adaptors have an internally threaded tubular body 6b extending from a slotted cap 6c, the slot 6a lying in a plane perpendicular to the tubular body 6b. Adaptor guide 15 may also be used as a driver for the pedicle screws, for example by providing a slot (not shown) in the distal end of guide 15 to receive a cross-bar that serves as a

handle.

After the pedicle screws are in place, the disc D is removed by percucaneous total discectomy. See, e.g., U.S. Patents 4,573,448, 4,545,374 and 4,679,459. Bone grafts are then packed between the vertebral plates, and the vertebrae are aligned into their desired position by compression, extension and/or angulation using a wrench (not shown) or other tool that securely grasps the proximal ends 1b of the screws and/or the adaptors 6.

When the vertebrae are properly aligned, they are locked in place by inserting the beam members 7 into the adaptors 6 and, in turn, locking the beam members 7 in place. Thus, one end of the beam member 7 is received in an adaptor 6 having a slot 6a open at one end and closed at the other, such as the upper adaptors 6 shown in Fig. 2, while the other end is received in an adaptor 6 having a slot open at both ends, such as the lower adaptors 6 shown in Fig. 2.

To insert the beam member 7 into the adaptors 6, a small incision (not shown), may, if necessary, be made in the patient's back adjacent the adaptor 6 having a slot 6a having two open ends. The beam member 7 is inserted into the subcutaneous tissue 40 via the incision and advanced through adaptors 6 until the distal end of the beam member 7 contacts the closed end of adaptor 6. If necessary, the beam members 7 may be bent to allow the beam member 7 to be received by the adaptors 6. Each beam member 7 is locked in place in adaptors 6 by set screws (not shown) or by crimping the adaptors 6 and the ends of the beam member 7 or by any other suitable detachable locking means. The incision is then closed.

It is presently preferred that the adaptor cap 6 have a low profile, i.e. with a small thickness relative to its length and width. Preferably the cap 6c has a substantially flat top and flat underside as shown, but other configurations may be used as long as the cap 6 is proportioned to lie beneath the skin of the patient without substantially violating the skin and/or the lumbar fascia 20. Thus, if the beam members 7 are in the form of rods 16 (Fig. 11), the cap 6 may still be flat but a suitable cylindrical slot (not shown) will be used.

Suitably, the guide wire may be about 10 to 12 inches long while the cannulated obturator 11 may be about 6 to about 7 inches long and about 7mm in diameter, with a lumen 11a sized to slide over the guide wire. The access cannula 12 may be about 5 to about 6 inches long with an inside diameter of about 7mm. The cannulated drill 13 also has a lumen 13a sized to slide over the guide wire and will have an outside diameter somewhat smaller than the outside diameter of the pedicle screw.

The pedicle screw 1 may have an outside diameter of about 5 to about 6.5mm and may suitably be from about 45 to about 70mm in total length, with a distal portion 1c of about 20 to about 45mm carrying a bone screw in thread form and the proximal portion being threaded to receive the adaptor 6. The tubular body 6b of the adaptor 6 may be about 15 to about 30mm long, with a cap 6c of about 30x30mm square and about 4 to 10mm thick. The slot 6a must accommodate the beam member 7. Plates of about 5 to about 10mm wide by about 35 to about 90mm long are suitable, the thickness of the plates 7 being about 2 to about 5mm. Rods 16 of about 5 to about 7mm in diameter and 35 to about 90mm long are also suitable. Anatomical variations of a particular patient may require the use of different dimensions.

While the drawings show for convenience the fixation of only two vertebrae, it is to be understood that more than two vertebrae may be fixed. For example, when two intervertebral discs are to be removed, say between vertebrae L1, L2 and L3, pedicle screws 1 will be implanted in the pedicles of the three vertebrae. The pedicle screws rising from the L1 or L3 vertebra will carry an adaptor 6 having a slot closed at one end, while the other pedicle screws will carry an adaptor 6 having a slot open at both ends. A longer beam member 7 is then slid through the adaptors 6 and locked into place as described above. Moreover, the surgeon may elect to fix three vertebrae even if only one disc is to be removed.

While the present invention has been illustrated in the accompanying drawings in terms of the fixation of adjacent lumbar vertebrae, it is to be understood that the same procedures are followed for the fixation of adjacent thoracic vertebrae, of adjacent thoracic and lumbar vertebrae and of the L5 and S1 vertebrae. In each case, the procedure is effected percutaneously as described above. That is, the center of each pedicle to be implanted with a pedicle screw is located fluoroscopically, the pedicle screws are implanted percutaneously as described above and the proximal ends of the pedicle screws are linked together beneath the skin at or preferably flush with the muscle fascia as described above. If considered desirable by the surgeon, the beam members and/or the pedicle screws may be cross-linked together, such as by the use of 1.5mm cross-wires.

Moreover, while the kit 50 is illustrated as containing the screws, beam members and adaptors, the same or auxiliary kits may be provided with the instruments used to carry out the surgical procedure, such as the instruments shown in Figs. 3-8 and 10.

10

15

20

25

30

35

45

50

Claims

- A pedicle screw (1) for percutaneous internal fixation of vertebrae, comprising proximal and distal ends (1b, 1a) and sized to enable the distal end (1a) to be screwed into the medullary canal (2) of a pedicle (3) of a vertebrae (4) with the proximal end (1b) thereof lying adjacent the fascia (20) of a patient.
- A pedicle screw according to claim 1, wherein the distal portion thereof carries a bone screw thread (1c).
- A pedicle screw according to claim 1 or 2, wherein the proximal portion thereof carries means (1d) engageable with a pedicle screw driver.
- 4. A kit for percutaneous fixation of vertebrae of a patient, comprising a plurality of pedicle screws (1) of different sizes, yet of a size to enable the distal end (1a) of each screw (1) to be screwed into the medullary canal (2) of a pedicle (3) of a vertebra (4) with the proximal end (1b) thereof lying adjacent the fascia (20) of a patient.
- A kit according to claim 4, wherein said pedicle screws (1) are of different diameters.
- 6. A kit according to claim 4 or 5, wherein said pedicle screws (1 have distal portions carrying bone screw threads (1b) of different lengths.
- 7. A kit according to any one of claims 4 to 6, including a plurality of linkage means (6,7) proportioned to lie under the skin of the patient and operable to detachably link together the proximal ends (1b) of said pedicle screws (1) inserted into the pedicles (3) of said vertebrae (4).
- 8. A kit according to claim 7, wherein said linkage means comprises a plurality of beam members (7) and a plurality of adaptor means (6) for detachably securing said beam members (7) thereto, said adaptor means (6) being detachably fastenable to said proximal ends (1b) of said pedicle screws (1).
- 9. A kit according to claim 8, wherein said adaptor means (6) comprise a slotted cap (6c) and a tubular body (6b) extending therefrom, said slot (6a) lying in a plane perpendicular to said tubular body (6b), each of the slots being proportioned to receive a beam member (7), some of the caps (6c) having a slot (6a) open

at both ends and others having a slot open at one end and closed at the other.

- 10. A method for percutaneous fixation of vertebrae of a patient, which comprises posterolaterally entering the back of a patient percutaneously with a plurality of pedicle screws (1), screwing each pedicle screw (1) into the medullary canal (2) of the pedicles (3) of adjacent thoracic and/or lumbar vertebrae (4) or the pedicles of the L5 and S1 vertebrae, to a position where the proximal end (1b) thereof lies adjacent the fascia (20) of the patient; inserting first and second pedicle screw linkage means (6,7) under the skin of the back of the patient and detachably securing said linkage means (6,7) to said proximal ends (1b) of said screws (1) on the same side of the spinous processes of said vertebrae to restrict relative movement between said vertebrae.
- 11. A method for percutaneous fixation of a pair of lumbar vertebrae of a patient, which comprises posterolaterally entering the back of a patient percutaneously and forming an opening in the cortical bone of each said pair of lumbar vertebrae at the juncture of the base of the transverse process and the proximal articular process of said vertebrae, said openings providing entrances into the respective medullary canals (2) of the pedicles (3) supporting said processes; percutaneously screwing into each of said medullary canals (2) a pedicles screw (1) to a position where the proximal end (1b) thereof lies adjacent the lumbar fascia (20) of the patient, providing for each pedicle screw (1) an adaptor (6) having a slotted cap (6c) and a tubular body (6b) extending therefrom, said slot (6a) lying in a plane perpendicular to said tubular body (6b); fastening the tubular body (6b) onto the proximal end (1b) of each said pedicle screw (1) such that said adaptor cap (6) lies between the lumbar fascia and skin of said patient; sliding a beam member (7) under the skin and into the slots (6a) of said caps (6c); and detachably locking said beam members (7) to said caps (6c).

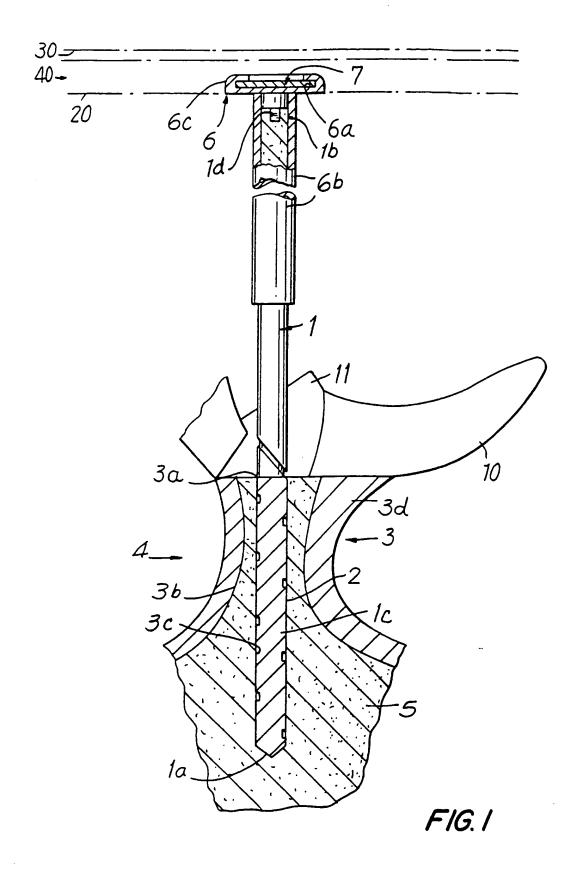


FIG. 2

